

IN THE CLAIMS:

1. (Currently amended) A composition comprising leukaemia inhibitory factor (LIF) ~~or a derivative or homologue thereof~~ and a stabilizing agent, additives for maintaining pH and isotonicity and one or more pharmaceutically acceptable carriers wherein the pH of the composition is between about 3.5 and 6.5.

2-5. (Canceled)

6. (Currently amended) A composition according to claim 1 wherein the stabilizing agent is an agent which increases or maintains the conformational stability of LIF ~~or its derivatives of homologues or functional equivalents thereof~~.

7. (Previously presented) A composition according to claim 6 wherein the stabilizing agent is selected from a polyhydric alcohol, a pharmaceutically acceptable salt, a buffer species, a sugar and a pharmaceutically acceptable polymeric compound.

8. (Original) A composition according to claim 7 wherein the polyhydric alcohol is sorbitol.

9. (Currently amended) A composition according to claim 6 wherein the ~~surfactant~~ stabilizing agent is an anionic, cationic, amphoteric or non-ionic surfactant.

10. (Original) A composition according to claim 9 wherein the surfactant is selected from a fatty alcohol, a glyceryl ester and a fatty acid ester of a fatty alcohol or other alcohol.

11. (Original) A composition according to claim 6 wherein the stabilizing agent is selected from a polysorbate, a polyoxyethylene derivative and a pharmaceutically acceptable polyoxyethylene-polyoxpropylene copolymer.

12. (Original) A composition according to claim 7 wherein the buffer species is selected from a phosphate, citrate and acetate buffer.

13. (Original) A composition according to claim 12 wherein the buffer species is a citrate or acetate buffer.

14. (Previously presented) A composition comprising leukaemia inhibitory factor (LIF), additives for maintaining pH and isotonicity and one or more pharmaceutically acceptable carriers and/or diluents and wherein the composition has a pH of between about 3.5 and 6.5.

15. (Previously presented) A composition according to claim 14 wherein the aggregation of LIF is reduced over time.

16-19. (Canceled)

20. (Previously presented) A composition according to claim 1 wherein LIF is present in an amount from about 0.1 µg/ml to about 100 mg/ml.

21. (Currently amended) A method for preparing a composition comprising leukaemia inhibitory factor (LIF) ~~or a derivative or homologue thereof and which~~ wherein said composition exhibits reduced deamidation and/or aggregation of LIF ~~or its derivative or homologues~~ over time, said method comprising admixing LIF ~~or its derivative or homologue~~ with a stabilizing agent and additives for maintaining pH and isotonicity.

22. (Currently amended) A method according to claim 21 wherein the stabilizing agent is an agent which increases or maintains the conformational stability of LIF ~~or its derivatives or homologues or a surfactant or functional equivalents thereof~~ or is a surfactant.

23. (Previously presented) A method according to claim 22 wherein the stabilizing agent is selected from a polyhydric alcohol, a pharmaceutically acceptable salt, a buffer species, a sugar and a pharmaceutically acceptable polymeric compound.

24. (Original) A method according to claim 23 wherein the polyhydric alcohol is sorbitol.

25. (Original) A method according to claim 22 wherein the surfactant is an anionic, cationic, amphoteric or non-ionic surfactant.

26. (Original) A method according to claim 25 wherein the surfactant is selected from a fatty alcohol, glyceryl ester and a fatty acid ester of a fatty alcohol or other alcohol.

27. (Canceled)

28. (Previously presented) A method according to claim 21 wherein the additives for maintaining pH and isotonicity are selected from a phosphate, citrate and acetate buffer.

29. (Previously presented) A method according to claim 28 wherein the additives for maintaining pH and isotonicity are citrate or acetate buffer.

30. (Previously presented) A method according to claim 21 further comprising adjusting the pH to between about 3.5 and about 6.5.

31. (Canceled)

32. (Currently amended) A method according to claim 21 further comprising admixing at least one or more of a pharmaceutically acceptable carriers and/or diluents carrier or diluent.

33. (Canceled)

34. (Previously presented) A method according to claim 54 wherein the stabilizing agent is selected from a polyhydric alcohol, a pharmaceutically acceptable salt, a buffer species, a sugar and a pharmaceutically acceptable polymeric compound.

35. (Previously presented) A method according to claim 34 wherein the polyhydric alcohol is sorbitol.

36. (Currently amended) A method according to claim 34 wherein the ~~surfactant~~ stabilizing agent is an anionic, cationic, amphoteric or non-ionic surfactant.

37. (Previously presented) A method according to claim 36 wherein the surfactant is selected from a fatty alcohol, glyceryl ester and a fatty acid ester of a fatty alcohol or other alcohol.

38. (Previously presented) A method according to claim 54 where the stabilizing agent is selected from a polysorbate, a polyoxyethylene derivative or a pharmaceutically acceptable polyoxyethylene-polyoxypropylene copolymer.

39. (Previously presented) A method according to claim 34 wherein the buffer species is selected from a phosphate, citrate and acetate buffer.

40. (Previously presented) A method according to claim 39 wherein the buffer species is a citrate or acetate buffer.

41. (Previously presented) A method according to claim 54 where the pH of the composition is between about 3.5 to about 6.5.

42. (Previously presented) A method according to claim 41 wherein the pH is

between about 4.5 and about 5.5.

43. (Previously presented) A composition according to claim 13 wherein LIF is present in an amount from about 0.1 $\mu\text{g/ml}$ to about 100 mg/ml.

44. (Previously presented) A composition according to claim 1 wherein the pH of the composition is between about 4.5 and 6.5.

45. (Previously presented) A composition according to claim 44 wherein the pH of the composition is between about 4.5 and 6.0.

46. (Previously presented) A composition according to claim 6 wherein the stabilizing agent is a surfactant.

47. (Previously presented) A composition according to claim 9 wherein the stabilizing agent is polysorbate 20 and/or polysorbate 80.

48. (Previously presented) A composition according to claim 14 wherein the composition has a pH of between about 4.5 and 6.5.

49. (Previously presented) A composition according to claim 48 wherein the composition has a pH of between about 4.5 and 6.0.

50. (Previously presented) A method according to claim 23 wherein the stabilizing agent is selected from a polysorbate, a polyoxyethylene derivative and a pharmaceutically acceptable polyoxyethylene-polyoxypropylene copolymer.

51. (Previously presented) A method according to claim 50 wherein the polysorbate is polysorbate 20 and/or polysorbate 80.

52. (Previously presented) A method according to claim 30 further comprising adjusting the pH to between about 4.5 and about 6.5.

53. (Previously presented) A method according to claim 30 further comprising adjusting the pH to between about 4.5 and 6.0.

54. (Currently amended) A method of preparing a composition comprising leukemia inhibitory factor (LIF) ~~or a derivative or homologue thereof which~~ wherein said composition exhibits improved chemical or physical stability of LIF, said method comprising admixing LIF or its derivative or homologue with a stabilizing agent.

55. (Previously presented) A method according to claim 42 wherein the pH is between about 4.5 and about 6.0.

56. (Previously presented) A composition according to any one of claims 1, 44 or 45 wherein the stabilizing agent facilitates reduced aggregation of LIF.

57. (Previously presented) A composition according to any one of claims 1, 44 or 45 wherein the stabilizing agent facilitates a reduction in the deamidation of LIF.

58. (Previously presented) A composition according to any one of claims 14, 48 or 49 wherein the deamidation of LIF is reduced over time.

59. (Previously presented) A composition according to any one of claims 14, 48 or 49 where the pH is maintained by the presence of a buffer species selected from a phosphate, citrate and acetate buffer.

60. (Previously presented) A composition according to claim 59 wherein the buffer species is a citrate or acetate buffer.